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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,453	11/16/2001	Laure Aurelian	53836-5003	4258

7590 05/12/2005

SUGHRUE MION
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037-3213

EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,453	AURELIAN ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 29-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/5/02</u> . | 6) <input type="checkbox"/> Other: _____ |

PD

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DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

Election/Restrictions

Applicant's election without traverse of Group II (Claims 5, 17-20, and 26-28) in the reply filed on January 14, 2005 is acknowledged. However, after further review the Office has decided to rejoin Claims 1-28 to be examined together due to overlapping subject matter. Hence, Claims 1-28 are rejoined and are under consideration.

Claims 29-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group(s). Election was made **without** traverse in the reply filed on January 14, 2005.

Applicants are reminded to cancel the claims to the non-elected Group(s).

Claim Rejections - 35 USC § 112

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "associated disease", what are the intended Associated diseases", the claim has been interpreted in light of the disclosure and nowhere does the disclosure indicates which associated symptoms are being ameliorated. This affects the dependent claims.

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Claim 2 is vague and indefinite for recitation of "increased" in parts a-d, this is a relative term, and is subject to varied interpretation. This affects the dependent claims.

Claim 11 recites the limitation "wherein said herpes simplex virus is a herpes simplex virus-2" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "wherein said herpes simplex virus is a herpes simplex virus-1" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 recites the limitation "wherein at least one immunogenic protein is administered" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "wherein said animal is a human" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "wherein said viral disease is herpes" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Aurelian et al (WO 99/36087). Aurelian et al taught ICP10 Δ PK deleted herpesvirus, which is deleted in the PK domain, and its utilization in eliciting a positive immune response in a suitable host including humans (see the abstract). They taught a method of preparation of the virus and method of

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administration of the virus (See Examples 1 and 2). In addition, they taught a challenge study wherein the deleted virus provided efficacy against the Herpesvirus infection (see Examples 6, and 7). Aurelian et al claimed the method of preventing clinical symptoms associated with herpesvirus (see all the claims). It is Office's position that the method of treating herpesvirus as taught by the above cited reference inherently (emphasis added) encompasses the method of now claimed invention. The Office has based this opinion on many factors one of which is the Applicant's own disclosure. The disclosure utilizes the same virus construct as taught by Aurelian et al, and simply observes the same effect as taught by the above cited reference, namely amelioration of symptoms of herpes simplex virus. What Applicants deem to be novel is in effect part and parcel of the method described by the cited reference. One cannot dispute the fact that once the product of Claim 1 of WO 99/36087 is utilized via the methods Claims 2-11, the same result, as now claimed invention, would be observed. In other words the now claimed invention is the inherent property of the methods taught by Aurelian et al. What Applicants deem as a new method is an observation on their part, and inherent observation of an old method is not patent eligible. Moreover, applicants are directed to *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202 (CAFC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new." This is the case here, while the Applicants may have "Observed" something interesting they have not invented anything new.

No Claims are allowed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

5/10/2005

ALL R. SALIMI
PRIMARY EXAMINER